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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------------------------------------------------------------------------------------------|-------------|-----------------------|---------------------|------------------|
| 09/871,974 | 06/04/2001 | Mathew A. Von Wronski | 2238-7 | 6852 |
| 35743 | 7590 | 02/25/2005 | EXAMINER | |
| KRAMER LEVIN NAFTALIS & FRANKEL LLP INTELLECTUAL PROPERTY DEPARTMENT 919 THIRD AVENUE NEW YORK, NY 10022 | | | AUDET, MAURY A | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1654 | |

DATE MAILED: 02/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|-------------------------|--------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/871,974 | VON WRONSKI ET AL. |
| | Examiner Maury Audet | Art Unit 1654 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM
THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 23 December 2004.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1,23-36 and 49 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1,23-36 and 49 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) Notice of References Cited (PTO-892)
 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
 Paper No(s)/Mail Date 12/23/2004.

4) Interview Summary (PTO-413)
 Paper No(s)/Mail Date. _____.
 5) Notice of Informal Patent Application (PTO-152)
 6) Other: _____.

DETAILED ACTION

Election/Restrictions

In the Office Action of 3/25/2004, the Examiner noted that “Additionally, Applicant was telephoned in order to specifically elect the specific composition as the invention (not species) drawn to elected invention of Group I. During a telephone conversation with Scott McNees on 3/2/2004 a provisional election was made with traverse to prosecute the invention of Formula I (A-L-B), wherein *A is a monomer and specifically TKPPR*; L is any linker; and B is the substrate phospholipids.

Applicant’s response has sought a clarification of the restriction requirement. A search of any monomer, multimer, or polymer of TKPPR and/or any analogues thereof is a distinct search since a substantial enough core does not run through the peptides that would be novel in itself (otherwise that core could be searched without an undue burden as well as the prior art reading upon that core and its species)(see claims filed 09/25/2001 to which the restriction requirement was based). Since all monomers, multimers, or polymers of TKPPR and/or any analogues thereof are unknown, as Applicant has not expressly written such into the specification, the restriction requirement could not be made to distinctly list out every potential group to which each peptide/analogue thereof would individually be placed. Thus, only a general restriction group could be made, and a requirement for an individual peptide/analogue to be elected to which the claims would be examined (the equivalent of a traditional restriction requirement where each group is listed with each identified peptide). Thus, based on Applicant’s claiming of unidentifiable peptides, the requirement format was proper and in line with traditional restriction

practice within the MPEP (Applicant is respectfully directed to MPEP Chapter 800 for guidance on restriction practice).

Thus, based on Applicant's election of the invention, Applicant is required to amend the claims to be drawn to the elected invention monomer A to be TKPPR only, or the succeeding response be non-responsive. The claims still read on TKPPR and any analogue of TKPPR, the latter of which falls outside the elected invention. Again, it is noted at the outset, that all pending claims, namely claims 1, 23-36, and 49, have only been searched and examined on the merits as being drawn to the elected composition (and specifically only TKPPR as the monomer A). The restriction requirement is made FINAL.

Claim Rejections - 35 USC § 112 1st Scope of Enablement

The rejection of claims 1, 23-36, and 49 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the peptide TKPPR as monomer A, does not reasonably provide enablement for any analogue of TKPPR as monomer A, in the invention's composition or method of ultrasound imaging, is maintained for the reasons of record. Applicant's elected invention comprises a *monomer* of TKPPR, not a monomer of a TKPPR analogue (see previous action discussing election of the invention, not species, of monomer TKPPR, by Scott McNees on 3/2/2004). Therefore, Applicant's arguments are moot and have not been considered. (See also discussion above under Election/Restrictions).

Claim Rejections - 35 USC § 103

The rejection of claims 1, 23-36, and 49 under 35 U.S.C. 103(a) as being unpatentable over Barbera-Guillem (US 6,333,110) in view of Pollak (US 5,789,555).

Barbera-Guillem teaches an imaging agents (i.e. title; abstract) using [A] peptides as targeting molecules (col. 4, line 60 and col. 5, line 1), [L] linkers (col. 6, lines 10-58), and [B] substrates such as phospholipids (col. 4, lines 43 and 54) (and like Pollak, classified in class 424; cover page).

As discussed in the previous actions, Pollak teaches *monomer* targeting peptides comprising 3 to 50 amino acids such as the 5-mer TKPPR (col. 3, lines 55-65). Pollack also teach such peptides as TKPPR conjugated to a linker (e.g., col. 4, lines 51-67 to col. 5, lines 1-10). Additionally, Pollak also teaches a method of using this composition for diagnostic/radiodiagnostic imaging (e.g., col. 1, lines 12-32; col. 5, line 56)(see entire specification).

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to use the targeting peptide TKPPR as the peptide of Barbera-Guillem, because Pollak teaches the advantageous use of the targeting peptide TKPPR for tissue targeting in imaging agent compositions.

From the teachings of the reference, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Maury Audet whose telephone number is 571-272-0960. The examiner can normally be reached from 7:00 AM – 5:30 PM, off Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached at 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197.

MA, 02/19/2005



CHRISTOPHER R. TATE
PRIMARY EXAMINER